

REMARKS

Reconsideration of the above-identified application in view of the above amendments and the following remarks is respectfully requested. Claims 1-3 and 5-63 are currently pending, with claims 1-3, 5-11, 27-42, and 58-61 being allowed. By the present amendment, claims 25 and 56 are amended to correct dependency. The above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Telephone Interview

Applicants thank the Examiner for conducting a telephone interview on August 26, 2005, to discuss the new bases of rejection raised in the Office Action July 28, 2005, which withdrew the previous allowance of all claims. Applicants note that the bases of the new rejections were discussed, and the Examiner agreed that the double patenting objection should be withdrawn in light of this discussion.

Rejection Under 35 U.S.C. § 112

Claims 25 and 56 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in their definition of the polycationic moiety "Y," which is recited in claims 23 and 54. Specifically, the Examiner submits that certain amino acid residues recited in claims 25 and 56 lack cationic side chains, which could result in "Y" not being cationic.

Applicants respectfully traverse this basis of rejection, and submit that the amino acid residues recited in claims 25 and 56 meet the definition of the polycationic moiety "Y" and, therefore, satisfy the requirements of the second paragraph of Section 112. As described in the instant specification, *e.g.*, page 20, line 5, the polycationic moiety, "Y," refers to a compound, derivative, or functional group having a positive charge at a selected pH, preferably physiological pH. Contrary to the Examiner's conclusion, Applicants submit that each of the recited amino acid residues contains a functional group having a positive charge at physiological pH. For example, lysine has two amino functions with pKa's of 9.06 and 10.54; arginine has two amino functions with pKa's of 9.04 and 12.48; asparagine has an amino group with a pKa of

8.80; and glutamine has an amino group with a pKa of 9.13. Applicants also note that it is not necessary for a cationic group to be located on a side chain on an amino acid residue, since the amino acids are not required to be linked to the hydrophilic polymer "W" by amide bonds. Accordingly, an amino acid residue can also be linked, *e.g.*, by ester or ether bonds to the carboxyl oxygen, thereby clearly providing a cationic group on "Y." Accordingly, the skilled artisan would appreciate that each of the recited amino acid residues meets the definition of a polycationic moiety, according to the instant specification. In addition, Applicants submit that one of skill in the art would also appreciate that combinations of lysine, arginine, asparagine, glutamine, and derivatives thereof, are also polycationic moieties, as defined in the instant specification.

Applicants respectfully request that the Examiner reconsider and withdraw this basis of rejection, in light of these remarks.

Double Patenting Objection

Claims 12 and 43 are objected to under 37 C.F.R. § 1.75 for allegedly being substantial duplicates of claims 1 and 33, respectively.

Applicants respectfully traverse this basis of objection and submit that claims 12 and 43 are not substantial duplicates of claims 1 and 33, respectively. Applicants note that claims 12 and 43 are directed to a nucleic acid-lipid particle, wherein the conjugated lipid of the claimed particle has the formula, A-W-Y. In contrast, base claims 1 and 33 recite a Markush group of conjugated lipids, which includes: a PEG-lipid; an ATTA-lipid; and a cationic-polymer-lipid conjugate having the formula, A-W-Y. Thus, the base claims do not require all forms of conjugated lipids to have the formula A-W-Y, and dependent claims 12 and 43 are, thus, further limiting. Accordingly, Applicants submit that claims 12 and 43 are not substantial duplicates of claims 1 and 33, respectively. In light of these comments and the telephone interview, Applicants respectfully request that this basis of objection be reconsidered and withdrawn.

Claim Objections

Claims 13-26, 44-57, and 62-63 are objected to for depending from objected-to base claims. Applicants respectfully traverse this basis of objection and submit that since claims

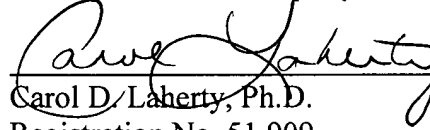
12 and 43 are allowable, for the reasons discussed above, claims 13-26, 44-57, and 62-63 are proper. Applicants further note that claims 62 and 63 depend from claim 33, which is not objected to. Applicants respectfully request that this basis of objection also be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all of the claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. Applicants again thank the Examiner for his willingness to conduct a telephone interview to address the new issues raised in the Office Action of July 27, 2005, and encourage the Examiner to contact the undersigned at the number below, if he believes any issues remain.

Respectfully submitted,

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